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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,421	03/11/2005	Hisashi Narimatsu	0760-0337PUS1	6315

2292 7590 05/18/2006

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,421	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/04, 11/04, 2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP03/03044 filed on 3/14/2003.

The preliminary amendment filed on 2/21/2006 amending claims 1 and 8, canceling claims 17-19 and 27-30 is acknowledged. Claims 1-16 and 20-26 are pending and are present for examination.

Applicant's election with traverse of Group I, Claims 1-7, drawn to an isolated polypeptide N-acetylglucosamine transferase and SEQ ID NO: 1 in the response filed on 2/21/2006 is acknowledged.

The traversal is on the ground(s) that if claims of Group I are allowable, the claims of Group II be rejoined. However, Group II is not drawn to a process of making or using the product of Group I but rather drawn to an isolated polynucleotide encoding the polypeptide N-acetylglucosamine transferase. Group I and II are each independent and distinct and lack of unity exists as discussed in the previous office action. Restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 8-16 and 20-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in communication filed on 2/21/2006.

Claims 1-5 and 7 are under consideration and are being examined herein.

Claim Objections

Claims 1-5 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 is not further limiting of claim 1.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is not further limiting of claim 1.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 is not further limiting of claim 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply

with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 7 are directed to a genus of an isolated polypeptide of SEQ ID NO: 1 having activity to transfer N-acetylglucosamine to a non-reducing terminal of Galβ1-4Glcβ1-4GlcNAc having one or more amino acids substituted or deleted or inserted or added to SEQ ID NO: 1. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches the structure of only three representative species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a polypeptide having activity to transfer N-acetylglucosamine to a non-reducing terminal of Galβ1-4Glcβ1-4GlcNAc. Given this lack of description of representative species encompassed by the genus of DNAs used in the claim, the specification fails to sufficiently

describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide having activity to transfer N-acetylglucosamine to a non-reducing terminal of Galβ1-4Glcβ1-4GlcNAc of SEQ ID NO: 1, does not reasonably provide enablement for any polypeptide or any polypeptide having one or more amino acids substituted or deleted, or inserted or added to SEQ ID NO: 1 or any polypeptide having 70% or 90% sequence homology to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-5 are so broad as to encompass any polypeptide having activity to transfer N-acetylglucosamine or any polypeptide having one or more amino acids substituted or deleted or inserted or added to SEQ ID NO: 1 while claim 3 encompasses any polypeptide having 70% sequence homology to SEQ ID NO: 1. Claim 4 recites any polypeptide having 90% sequence homology to SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptide broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in

which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only two polypeptides having activity to transfer N-acetylglucosamine.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any polypeptide having activity to transfer N-acetylglucosamine or any polypeptide having one or more amino acids substituted or deleted or inserted or added to SEQ ID NO: 1 or any polypeptide having 70 or 90% sequence homology to SEQ ID NO: 1 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting N-acetylglucosamine transfer activity; (B) the general tolerance of a polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any polypeptide residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope

of the claims broadly including any polypeptide having activity to transfer N-acetylglucosamine or any polypeptide having one or more amino acids are substituted or deleted, or inserted or added to SEQ ID NO: 1 or any polypeptide having 70 or 90% sequence homology to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any polypeptide having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Piller et al. (J Biol Chem. 1983 Oct 25; 258(20): 12293-9, see IDS). Piller et al. teach an UDP-GlcNAc:Gal beta 1-4Glc(NAc) beta 1-3N-acetylglucosaminyltransferase, its identification and characterization in human serum. Piller et al. also teach that 1-3-N-Acetylglucosaminyltransferase having activity transferring N-acetylglucosamine residues from

UDP-GlcNAc to terminal Gal beta 1-4Glc(NAc) structures in oligosaccharides, glycoproteins, glycolipids, and proteoglycans wherein the said enzyme recognizes specifically the free terminal structure Gal beta 1-4Glc(NAc). Piller et al. further teach that N-acetylglucosamine is incorporated only into those substrates having free terminal Gal beta 1-4Glc(NAc) structures.

Claim 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Togayachi et al. (J Biol Chem. 2001 Jun 22; 276(25): 22032-40, Epub, Mar 30, 2001, see IDS). Togayachi et al. teach molecular cloning and characterization of UDP-GlcNAc: lactosylceramide beta 1,3-N-acetylglucosaminyltransferase (beta 3Gn-T5) from human. Togayachi et al. also teach that enzyme has beta3Gn-T motifs and further showed that the beta3Gn-T5 exhibits strong activity to transfer GlcNAc to glycolipid substrates.

Claim 1-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (WO 02/26950, publication 4/4/2002, priority 60/244,025, 10/27/00). Lal et al. teach a human glycosyltransferase protein (SEQ ID NO: 10) having 401 amino acid residues, which is 99.9% (one amino acid mismatch out of 401 amino acid) identical to SEQ ID NO: 1 of the instant application. Lal et al. also teach UDP-glucosaminyltransferase activity of the polypeptide. Although Lal et al. do not disclose the transfer of N-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNac group, the protein of Lal et al. inherently anticipates the said transferring characteristics as recited in claims 1 and 7.

Claim 1-5 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Kataoka et al. (GenBank Accession No. AF502429 (nucleic acid) and AAM61770 (protein), created 6/25/2002, "beta 1,3-N-acetylglucosaminyltransferase 7" and "A novel beta1,3-N-acetylglucosaminyltransferase involved in invasion of cancer cells as assayed in vitro", Biochem

Biophys Res Commun. 2002 Jun 21; 294(4): 843-8, see IDS). Kataoka et al. teach a human beta1,3-N-acetylglucosaminyltransferase glycosyltransferase cDNA encoding a protein having 401 amino acid residues, which is 100% identical to SEQ ID NO: 1 of the instant application. Kataoka et al. also teach that the polypeptide has the activity to transfer beta1,3-N-acetylglucosamine group through beta 1,3 linkage. The protein of Kataoka et al. inherently anticipates all the transferring characteristics as recited in claims 1 and 7.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

Status of the claims:

Claims 1-5 and 7 are pending.

Claims 1-5 and 7 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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